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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,305	03/19/2001	Roger Read	047763-5017	5146
9629	7590	02/01/2005	EXAMINER	
MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004			CHANG, CELIA C	
			ART UNIT	PAPER NUMBER
			1625	
DATE MAILED: 02/01/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/673,305		READ ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Celia Chang		1625	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 24 August 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1,2,4-17,22,23,25-29,35,37-40,42-45 and 47-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 4,5,15,16,25 and 26 is/are allowed.
- 6) ☐ Claim(s) 1,2,17,22,23,25,27-29,37-40,42-45 and 47-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

1. Amendment and response filed by applicants dated Aug. 24, 2004 have been entered and considered carefully. Claims 1, 2, 4-17, 22, 23, 25-29, 35, 37-40, 42-45, 47-50 are pending. Claims 3, 18-21, 24, 30-34, 36, 41 and 46 have been canceled.

2. Applicant's arguments with respect to claims 1, 2, 4-17, 22, 23, 25-29, 35, 37-40, 42-45, 47-50 have been considered but are moot in view of the new grounds of rejection.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 17, 27-29 and 50 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by CA 128:34643.

See RN structures attached.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 17, 50, 27-29, 22-23, 25, 37-40, 42-45, 47-49 are rejected under 35 U.S.C. 102(b) as being anticipated by WO96/29392.

See compounds at pages 1/6, 3/6 to be used in claims 18-24 composition. Please note that the R6 is propyl and di-chloro substituted compounds have been proviso out but not the other of page 1/6, , the R6 is propyl compound on page 3/6 have been proviso our but not these other compounds when R6 is no propyl but falls within the claims.

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5. Claims 22-23, 35, 37-40, 42-45, 47-49 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 4 of U.S. Patent No. 6,635,692 (Please note that Peter Steinberg is evidenced by US 2004/0072898 to be of same assignee). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims fully embraced the issued claim.

Please note that the issued claim 4 claimed compositions of compounds fully embraced by the instant claims. The instant claims embraced compositions without limitation of the other components in the composition thus fully embraced the more limited carrier of the issued claim. Especially, the surface coating composition are known in the art to be explicitly polymeric containing as disclosed in the specification.

6. Claims 22-23, 35, 37-40, 42-45, 47-49 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 17-19 of commonly assigned copending Application No. 10/434,193 US 2004/0072898. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims contain species which anticipated the instant claims, see compounds delineated in figures 2. The copending claims are fully embraced by the instant claims since the copending claims are limited to pharmaceutical composition while the instant claims have no limitation of the carrier.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The scope of the claim is ambiguous and indefinite with respect to the inclusion of "each substituent can be substituted or unsubstituted, straight chain or branched chain and either hydrophobic or hydrophilic or fluorophilic". Please note that *no definitions* are found in specification for the terms "hydrophobic or hydrophilic or fluorophilic" i.e. as a structural moiety. While the functional language makes the scope unclear because the term "each substituent is

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substituted or unsubstituted, straight chain or branched chain” defines structure. The terms “either hydrophobic or hydrophilic or fluorophilic” makes the structural definition confusing. Is it only when it is substituted and becomes hydrophilic, hydrophobic or fluorophilic is the substitution within the claim? Or is it irrespective of the functional outcome a substitution is inclusive? While a substituted alkyl is clear to one having ordinary skill in the art, the scope hydrophilic substituted alkyl in absence of clear definition lacks antecedent basis and makes the scope indefinite. If upon substitution, the alkyl moiety becomes hydrophobic, with or without the superfluous functional definition, such moiety is included by the term “substituted alkyl”. It is recommended, the indefinite and superfluous terms “either hydrophobic or hydrophilic or fluorophilic” be deleted.

8. Claims 22-23, 35, 37-40, 42-45, 47-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 22-23, 35, 37-40, 42-45, 47-49 are composition claims with only “one” ingredient. It is unclear whether the other ingredient in the composition are inert carrier or other active substance. If these are multiple active component compositions then such multiple active ingredient composition and a single active ingredient composition are restrictable. If these are compositions with particular carrier, then, the carrier should be particularly pointed out.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manny CA 128:34643 or Kuelleberg CA 126:4540 in view of Cueto et al., Kotsuki et al. Manny et al. and WO 96/29392.

Determination of the scope and content of the prior art (MPEP §2141.01)

Manny CA 128 or Kuelleberg CA 126 disclosed anticipatory compounds made from the starting material fimbrolide (RN 63025-36-5).

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the claims and the prior art is that a broad variation of compounds made with specific choices of reagents are claimed. Cueto et al., Kotsuki et al. Manny et al. and WO 96/29392 disclosed similar process for making structurally close compounds with the identical starting material with variations of solvents, dehydrating agents and halogenation agents, especially, WO 96/29392 disclosed that the furanone family of compounds can be made by conventional method known in the art (see p. 4 third paragraph).

Finding of prima facie obviousness—rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art given anticipatory and analogous compounds made by processes using fimbrolide and the conventional teaching in chemistry on dehydrating agents, halogenating agents and solvents would be motivated to employ empirical operable modification to the process since such modifications are recognized in the chemical art to be an effect oriented optimization of reaction parameter within the skill of the art. In re SZUMSKI 133 USPQ 551, 302 F2d 753.

8. Claims 4-5, 15-16, 25-26 are allowable. The claims contain compounds or process of using compounds of claims 4-5 in making other compounds which are neither anticipated nor rendered obvious by the art of record.


9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*OACS/Chang*  
*Jan. 27, 2004*

  
*Celia Chang*  
*Primary Examiner*  
*Art Unit 1625*